REMARKS

The presently claimed invention features: claims drawn to methods for determining whether an individual has the 6/6 genotype, the 6/7 genotype, or the 7/7 genotype at the UDP glucuronosyltransferase subfamily 1 (UGT1) locus (claims 15-20), methods for screening patients for inclusion in a clinical drug trial (claim 21), and certain primers (claim 22). Such determinations are useful, for example, in the design and conduct of clinical trials because certain genotypes are associated with increased serum bilirubin, for example, under conditions of restricted diet.

Claims 2-14 have been cancelled. New claims 15-22 have been added. Support for new claim 15 is found throughout the specification, for example, at pages 12-13 and in Figure 1. Support for new claims 16-20 is found throughout the specification, for example, at pages 3-5. Support for new claims 21 and 22 is found, for example, at pages 12-13 and 3-5 of the specification.

Applicant appreciates the notification that the Examiner found previously pending claim 13 to be allowable because the claim specifies primer pairs that are not found the in prior art.

Rejections Under 35 U.S.C. §103

The Examiner rejected previously pending claim 12 as obvious in view of Bosma et al. (*New England J. Med.* 333:1171, 1995) taken with the Stratagene Catalog (1988). Claim 12 has been cancelled, obviating this rejection.

The Examiner rejected claims previously pending 2-11 and 14 as obvious in view of Bosma et al. (*supra*) taken with Sibille et al. (*Eur. J. Clin. Pharmacol.* 39:475, 1990). Claims 2-11 and 14 have been cancelled, obviating this rejection.

New Claims 15-22

New claims 15-22 are drawn to methods for determining whether an individual has the 6/6 genotype, the 6/7 genotype, or the 7/7 genotype at the UDP glucuronosyltransferase subfamily 1 locus (claims 15-20), methods for screening patients for inclusion in a clinical drug trial (claim 21), and certain primers (claim 22). All of the presently claimed methods entail the use of certain specific primer pairs used to amplify genomic DNA. Claim 21 is method claim

that includes essentially the limitations of previously pending claim 13 and the claims (i.e., previously pending claims 2 and 7) from which previously pending claim 13 depended. Claim 22 is drawn to the primers of previously pending claim 13. Accordingly, it is believed that new claims 15-22 are allowable.

Conclusion

Attached is a marked-up version of the changes being made by the current amendment.

Applicant asks that all claims be allowed. Enclosed is a Petition for Extension of Time with the appropriate fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 5 Sept 2002

Anita L. Meiklejohn, Ph.D.
Reg. No. 35,283

Fish & Richardson P.C.
225 Franklin Street
Boston, Massachusetts 02110-2804
Telephone: (617) 542-5070
Facsimile: (617) 542-8906

Version with markings to show changes made

In the claims:

Please cancel claims 2-14.

Please add new claims 15-22.

In the abstract:

[The invention provides a method for improving the efficacy of drug trials, the method comprising the step of screening samples from potential participants for the genetic basis of Gilbert's Syndrome and eliminating or including potential participants in a drug trial in the knowledge of them possessing or not possessing the genetic basis of Gilbert's Syndrome.] Methods for determining the genotype of an individual within the UPD glucuronosyltransferase subfamily 1 locus are disclosed. Certain of the genotypes are shown to be associated with elevated serum bilirubin and/or Gilbert's Syndrome. Also disclosed are methods for taking such determinations into account during the design and conduct of a clinical trial.